

**Meeting of the OIE ad hoc Group
TO REVIEW THE bovine spongiform encephalopathy CHAPTER IN THE
OIE TERRESTRIAL ANIMAL HEALTH CODE**

Paris, 15-16 April 2004

Adopted Agenda

1. Update on significant scientific advances on BSE and its relationship with other TSE's
 2. Proposals for revision of BSE-risk categories in the 2003 *Terrestrial Animal Health Code* chapter
 3. Proposals for revision of the other aspects of the 2003 *Terrestrial Animal Health Code* chapter on BSE
 4. Proposals for revision of the BSE surveillance Appendix in the 2003 *Terrestrial Animal Health Code*
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**PROPOSED BOVINE SPONGIFORM ENCEPHALOPATHY CATEGORISATION
SYSTEM**

The *ad hoc* Group believed that the purpose of a bovine spongiform encephalopathy (BSE) categorisation system was to enable and encourage appropriate risk mitigation measures (based on a risk assessment as described in Article 2.3.13.2) to be applied to commodities for trade so that they would present a negligible risk to the importing country.

The *ad hoc* Group believed that the use of three categories offered the best science-based practicable approach to the epidemiology of BSE, with an emphasis on the safety of commodities for trade rather than on a pragmatic classification of country status. It believed that a change in emphasis would be best achieved through an expanded list of conditions for safe trading of commodities.

In this context, the *ad hoc* Group believed that it was appropriate to emphasize the use of surveillance as specified in Appendix 3.8.4. to supplement data provided by risk assessments.

The *ad hoc* Group proposed the following three categories:

a) **Category 1 - negligible BSE risk or negligible BSE risk without mitigating measures**

A country or zone/compartiment where a combination of surveillance and risk assessment confirms that commodities need no risk mitigation measures to present a negligible risk of transmitting the BSE agent.

b) **Category 2 - controlled BSE risk or negligible BSE risk with mitigating measures**

A country or zone/compartiment where a combination of surveillance and risk assessment confirms that the risk factors present are being mitigated, and that commodities present a negligible risk of

transmitting the BSE agent due to the application of additional commodity-specific risk mitigation measures. The general and commodity-specific risk mitigation measures applied are commensurate with the risk factors identified and are subject to regular review, based on the latest scientific information.

c) Category 3 - *undetermined BSE risk*

A country or zone/compartiment not complying with the requirements of Category 1 or 2.

The *ad hoc* Group proposed a broad second category with no arbitrary distinctions, due to the difficulty of estimating accurately the prevalence of BSE infection and the relative lack of importance of prevalence in relation to rendering commodities safe. A country or zone/compartiment in this category would need to demonstrate:

- an effective ruminant to ruminant feed ban;
- routine ante-mortem and post-mortem veterinary inspection;
- SRM removal and destruction to reinforce the effectiveness of the feed ban;
- completion and regular review of a risk assessment in accordance with Article 2.3.13.2;
- implementation of a surveillance programme (in accordance with Appendix 3.8.4) to supplement data provided by the risk assessment;
- routine examination and notification of clinical cases;
- access to adequate laboratory capacity;
- implementation of an awareness programme in accordance with Article 2.3.13.2.

The third category still offered the opportunity for trade in certain commodities for those Member Countries where the required risk assessment and/or surveillance were not within their capabilities at the time. In order to qualify for category 2, a country or zone/compartiment in category 3 would need to demonstrate that all criteria for category 2 had been in place for an appropriate period of time.

The *ad hoc* Group noted that risk mitigation measures in line with the current five categories (based primarily on differences in apparent prevalence of BSE infection) were not being implemented in practice. It believed that, with the three proposed categories being risk-based (with emphasis on a combination of risk assessment and surveillance), there would be less opportunity for subjective interpretation.

The *ad hoc* Group will develop procedures for countries or zones/compartiments moving from categories presenting a higher risk to those of lower risk. These procedures will be based on the outcomes of a risk assessment, and the quantity and duration of surveillance, to confirm compliance with the requirements of the lower risk category.

The *ad hoc* Group agreed that the *Terrestrial Code* should contain a list of commodities presenting a negligible likelihood of transmitting the BSE agent, either without any restrictions being applied or as a result of the application of risk mitigation measures. Accordingly, it proposed the following modifications to Article 2.3.13.1, subject to a revised categorisation system being adopted:

“*Veterinary Administrations* should authorise trade:

- 1) without BSE related restrictions and from all categories of countries or zones/compartiments regardless of their BSE status, in:
 - a) *milk* and *milk products*;
 - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

- c) hides and skins (excluding hides and skins from the head);
 - d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);
- 2) without BSE related restrictions from category 1 countries or zones/compartments, in all other commodities;
- 3) with BSE related restrictions, from categories 2 and 3 countries or zones/compartments, in:
 - a) for cattle under 30 months of age, boneless beef (muscle meat) from cattle subject to ante-mortem and post-mortem veterinary inspection and stunning conducted in accordance with Article 2.3.13.15;
 - b) for cattle over 30 months of age, boneless beef (muscle meat) from cattle subject to ante-mortem and post-mortem veterinary inspection and stunning conducted in accordance with Article 2.3.13.15, and with removal of all SRMs (in accordance with Article 2.3.13.19) in a hygienic manner;
 - c) for cattle of all ages, heart, liver and kidneys, and products made exclusively from these tissues, from cattle subject to ante-mortem and post-mortem veterinary inspection and stunning conducted in accordance with Article 2.3.13.15;
 - d) for cattle of all ages, bovine-derived tissues (other than those designated in Article 2.3.13.18), not intended for use in food or feed, cosmetics, pharmaceuticals including biologicals, or *in vivo* medical devices;
- 4) subject to the additional prescribed conditions relating to the BSE status of the cattle population of the *exporting country* or zone, from category 2 countries or zones/compartments, in:
 - a) cattle;
 - b) bone-in *fresh meat* and *meat products*;
 - c) gelatin and collagen prepared from bones;
 - d) tallow and tallow derivatives, and dicalcium phosphate.”

Proposed modifications to other aspects of the
OIE *Terrestrial ANIMAL HEALTH Code*
chapter and appendix on BOVINE SPONGIFORM ENCEPHALOPATHY

The *ad hoc* Group proposed some modifications to other aspects of the *Terrestrial Code* chapter and appendix on BSE, to better address the risk factors and to harmonise with the latest scientific information on BSE.

The *ad hoc* Group believed that references to an effective feed ban and the need for accurate record keeping should be included in Article 2.3.13.2.

The *ad hoc* Group proposed clearer wording for the paragraph addressing the ‘on-going awareness programme’.

The *ad hoc* Group discussed the BSE risks associated with the *in vivo* use of medical devices and with the use of bovine-derived tissues in industry (e.g. for the manufacture of bone china, soap, etc.) and proposed some changes to the release assessment in Article 2.3.13.2 to address such risks.

The *ad hoc* Group was not aware of new information questioning the safety of ‘protein free tallow’. Therefore, at this stage, the *ad hoc* Group did not believe that it was justified to propose a change to the text on tallow in the BSE chapter of the 2003 *Terrestrial Code*.

The *ad hoc* Group believed that the general approach should be that SRMs be removed from cattle in country or zone categories other than ‘free’ and ‘provisionally free’, as described in Article 2.3.13.19.

The *ad hoc* Group believed that the information available indicated that ‘bovine blood and blood by-products’ would be safe, subject to stunning being carried out in accordance with Article 2.3.13.15.

The *ad hoc* Group believed that, for the practical implementation of Article 2.3.13.3, the OIE should not recommend in c) ii) merely that ‘the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned’ (although this would be the science-based position) but that the feeding to ruminants of any *meat-and-bone meal* and *greaves* be banned, unless (in practice) bovine SRM removal and destruction requirements are in place. This was due to concerns over multiples streams of raw materials which may not have been separated adequately in feed manufacturing premises and over the presence of ruminant-derived *meat-and-bone meal* in the intestines of pigs and poultry at slaughter.

In point 2)b) of Article 2.3.13.4, the *ad hoc* Group recommended that feed cohorts be included in the definition to address cases where several are imported from the same herd and may have been exposed to the same contaminated feed in the exporting country. The *ad hoc* Group believed that the Canadian proposal for testing birth and feed progeny at the time of their death could yield valuable additional data but should not be compulsory.

The *ad hoc* Group noted that, in Article 2.3.13.5, the 24 months age cut off was not consistent with Table 1 in Appendix (30 months), but it believed that 24 months was the usual cut off point for census data; if the ages are aligned at 24 months, the *ad hoc* Group considered that the prevalence cut-off limits for the categories may need to be adjusted.

The *ad hoc* Group also recommended that the Code Commission clarify text in Article 3.8.4.1 regarding sub-populations, and address some apparent inconsistencies between the reference in that article to the need to sample from more than one sub-population and the references in Article 2.3.13.6 to the various sub-populations to be sampled.

The *ad hoc* Group also recommended that ‘and post-mortem inspection’ be added in Articles 2.3.13.14 and 2.3.13.15 to ensure a general minimum standard of hygiene at plants.

The *ad hoc* Group also recommended that, in point 5) of Article 2.3.13.16, the cut off age could be increased to 12 months as an effective feed ban was in place. It also recommended that points 2) to 4) of Article 2.3.13.17 be harmonised with the age cut offs in Article 2.3.13.19 by moving all to 12 months.

The *ad hoc* Group did not consider that there were sufficient new data to recommend a change from its previous recommendation to remove tonsils and intestine from cattle of all ages from moderate and high risk countries or zones, due to the presence of lymphoid tissue throughout the intestines.

The *ad hoc* Group indicated that progress in the European Union (EU) work on a statistically-valid surveillance programme for BSE would be monitored as a basis for reviewing and updating the appendix.

The *ad hoc* Group recalled that the purpose of the Appendix was to detect the presence of BSE and that it was therefore correct to:

- sample more than one sub-population;
- recognise that BSE is not unilaterally present in the first sub-population;
- propose a relative distribution of BSE among sub-populations;
- recognise that Table 1 is a highly optimistic interpretation based on the following (as described in Article 3.8.4.2)
 - . concentration of all BSE within that sub-population,
 - . an adult cattle mortality rate of 1%,
 - . prevalence of central nervous system (CNS) signs of 1% within dying adult cattle.

The *ad hoc* Group proposed a modification to the second paragraph of Article 3.8.4.2 to clarify the use of Table 1, as follows:

Table 1 indicates the minimum number of animals exhibiting one or more clinical signs of BSE that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. The calculations assume a prevalence of one BSE clinically affected animal per one million adult cattle, a mortality rate not exceeding one percent per year in adult cattle, and a prevalence of central nervous system (CNS) signs not exceeding one percent within dying cattle. In countries where these assumptions do not apply, a different sampling rate needs to be used to reach the same conclusions.

The *ad hoc* Group believed that the above supports the adoption of a revised surveillance approach which:

- recognises the apparent distribution of BSE among the three sub-populations (based on initial EU findings);
- recognises the need for sampling of all sub-populations (except healthy cattle at slaughter unless sufficient samples cannot be derived from other sub-populations);
- **recognises, on the basis of the EU CRL model or an equivalent examination of statistics derived from the sub-populations, the appropriate factors to be applied in the determination of the underlying prevalence of BSE in the cattle population.**